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Producers of Quality Nonprescription Medicines and Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
Formerly Nonprescription Drug Manufacturers Association

September 30, 1999

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 98N-0359: Program Priorities in the Center for Food Safety and Applied Nutrition

Dear Madam or Sir:

The Consumer Healthcare Products Association (CHPA) submits these written comments in response to FDA's notice in the September 1, 1999 Federal Register concerning Program Priorities in the Center for Food Safety and Applied Nutrition

The Consumer Healthcare Products Association (CHPA), formerly known as the Nonprescription Drug Manufacturers Association (NDMA), is a 118-year-old trade organization representing the manufacturers and distributors of national and store brand dietary supplements and nonprescription medicines. CHPA's membership includes over 200 companies involved in the manufacture and distribution of these self-care products and their affiliated services (e.g., raw material suppliers, research testing companies, contract manufacturing companies, advertising agencies, etc.).

98N-0359

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Executive Summary

Major Program Area

CFSAN should place safety first – enforcement, GMPs and AERs when setting its priorities for program activities in the year 2000. The refinement of the infrastructure of the Office of Special Nutritionals and other components of CFSAN should be part of this safety priority and be accomplished through creation of an overall strategic plan. [1]

"A" List

1) CHPA recommends in 2000 that CFSAN place publication of ANPR for GMPs as a top priority and consider the additional specific comments CHPA has developed in developing the NPR on dietary supplement GMPs. [2]
2) CHPA recommends in 2000 that CFSAN develop a written plan for and adopt a systems approach to AER management.[1]
3) Regarding claims, CHPA recommends in 2000 CFSAN re-propose the structure/function proposed rule as a focused regulatory statement that closely incorporates the specific intent of DSHEA per CHPA's comments to FDA on August 4, 1999, and omits the proposed confusing and ambiguous proposed criteria[3]. In addition, finalize its planned 1999 mid-year priority on the types of disclaimers for health claims, as directed by the courts in Person v. Shalala.
4) CHPA recommends that CFSAN further develop its administrative infrastructure relating to policies and procedures for meetings with external constituencies, AER systems management, advanced calendar for agenda topics for the Foods Advisory Committee, and providing more than two-weeks for developing comments to FDA

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1 CHPA's Comments of August 20, on CFSAN's Overall Strategic Plan for Dietary Supplements
[2] CHPA's Amended Comments on GMPs for Dietary Supplements
[3] CHPA's Comments of August 4, 1999 on FDA's Proposed Rule on Structure/Function Claims

proposals and stakeholder meetings.[1]

Detailed Comments

CHPA's detailed comments are organized according to the following outline:

Overview of CHPA's Comments on Year-2000 Program Priorities in the Center for Food Safety and Applied Nutrition

- **Priorities:** In setting its priorities for program activities, CFSAN should place safety first – enforcement, GMPs and AERs. The refinement of the infrastructure of the Office of Special Nutritionals and other components of CFSAN should be part of this safety priority and be accomplished through the creation of an overall strategic plan. While activity on issues pertaining to claims might proceed as priority is given to safety issues, its completion should be targeted further in the future than that for resolving the safety and operational issues.

FDA Question 1. With respect to products under the jurisdiction of CFSAN, do you believe there are issues that directly affect consumer safety that are not being adequately addressed?

CHPA Response.

- **Enforcement:** In passing DSHEA, Congress intended that consumers would use dietary supplements for health promotion, health maintenance and disease risk reduction (i.e., health claims). Consumer confidence is essential to product use. Allegations that the dietary supplement industry is "unregulated" or that FDA is not using its statutory authority to act can undermine consumer confidence. Therefore, foundational to CFSAN's overall strategy for dietary supplements is an effective enforcement policy that removes unsafe products from the marketplace and ensures truthful, not misleading, and substantiated claims on dietary supplements. As part of an overall strategy for dietary supplements, therefore, the complementary relationship between FDA and FTC should be reviewed and strengthened.

A public workshop for all stakeholders on this matter would be helpful to understand the current relationship between FDA and FTC and provide input on ways to further develop that relationship.

FDA Question 2. Within the 10 program areas identified previously, what specific activities do you believe should be top priorities for CFSAN and why?

CHPA Response.

- **Good Manufacturing Practices:** CHPA recommends that FDA place publication of ANPR for GMPs as a top priority in 2000 and consider the additional specific comments that CHPA has developed in developing the NPR on dietary supplement GMPs.

- Special *FDA-adopted* GMPs for dietary supplements are important for the following reasons: a) differing needs of dietary supplements vs. foods, specifically related to manufacturing processes, laboratory controls and QC/QA specifications, and b) there are at least three sets of GMPs now in use for dietary supplements, specifically, the food GMPs, the dietary supplement industry-proposed GMPs and GMPs used under the voluntary program of the National Nutritional Foods Association. *FDA-adopted* dietary supplement GMPs would lead to uniformity in how manufacturing processes are evaluated, and would raise the level of awareness among suppliers, manufacturers and distributors regarding the need for quality operations.

- **Adverse Experience Reporting:** Public discussion on putative safety issues relating to dietary supplements should appropriately focus on the science, not the quality of administrative methods used to document

AERs. Therefore, as stated in its May 27, 1999 comments to the House Committee on Government Reform, CHPA recommends that CSFAN:

- Create a written plan for and adopt a systems approach to AER management;
- Create written protocols and keep them updated, including detailed decision tree for filtering AERs;
- Create policy and procedures for timely sharing of serious AERs with affected companies;
- Establish specific CFSAN training manuals and procedures for quality collection, analysis and reporting of AERs;
- Review the core competency of the personnel who would operate different facets of an adequate AER system on dietary supplements;
- Re-engineer the public access to AER reports for dietary supplements;
- Ensure public input in the development of policies and procedures be used in CFSAN's systems approach to AER management.

- **Claims:** CHPA recommends the following as part of CFSAN's development of an overall strategy on dietary supplements:
  - Re-propose the structure/function proposed rule as a focused regulatory statement that closely incorporates the specific intent of DSHEA, appropriately amends FDA's proposed re-definition of disease per CHPA's comments to FDA on August 4, 1999, and omits the confusing and ambiguous proposed criteria. Specifically, as outlined in CHPA's comments on August 4, 1999, CHPA pointed out to CFSAN that the definitions of disease in 101.14 (re: NLEA) and in the proposed structure/function rule are overly broad, demonstrating that there is likely no "bright line" as FDA hopes to find. Therefore, CHPA recommends a definition of disease that encompasses both the adverse nature of disease, on one hand, and the concept of "natural state or process," on the other, in

order to better focus the issue of defining structure/function claims within the disease definition itself.

> CHPA's Proposed Definition of Disease: "... a disease is any adverse deviation from, or impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms, ~~including laboratory or clinical measurements~~ that are not characteristic of a ~~disease~~ natural state or process."
>
> *(Note: underlined portions are additions and strikeouts are deletions from FDA's proposed definition of disease.)*

"Any deviation" is too broad; "any ***adverse*** deviation" appropriately defines the nature of the deviation; "laboratory or clinical measurements" are redundant and included under the concept of "signs", and "not characteristic of a natural state or process" appropriately encompasses Congress' intent to allow health promotion/maintenance claims. CHPA also recommends natural state or process be defined by regulation, as follows:

> "A natural state or process is a life change or physiologic manifestation expected in the normal course of life progression."

- Development of an overall guidance on statements of nutritional support (structure/function) claims for dietary supplements, consistent with DSHEA and including and modeled after the FTC advertising guidance to industry.

- Finalize its planned 1999 mid-year priority on the types of disclaimers for health claims, as directed by the courts in Person v. Shalala

- **CFSAN's 3-to-5 Year Strategic Plan and Resources:** CFSAN's development of an overall strategy for dietary supplements should be undertaken as a 3-to-5 year plan and/or gaps analysis, which is typically viewed as a "living" document that appropriately evolves dependent on the changing climate. As part of such a strategic plan, CFSAN should define its human and fiscal resource needs, including expanded use of outside contractors (e.g., for AER management). As stated under priorities, CFSAN should concentrate on its overall strategic plan with safety first, followed by claims and other activities.

FDA Question 3. FDA needs to ensure that its research programs provide the scientific information upon which regulatory decisions are made. In CFSAN, what do you believe should be the highest priority areas for conducting research?

CHPA Response.

- CHPA understands that FDA is interested in conducting consumer research on dietary supplement use. This should be a secondary priority. If CFSAN chooses to move forward in this area, then the extensive experience of industry should be brought to bear in joint consultations with outside organizations such as Prevention. The Prevention Magazine, which conducts regularly consumer attitudinal research, should be accessed for input. In any case, FDA should publicly develop any consumer research agenda, ensuing that any activity in this area does not in anyway supersede the priorities outlined under the "A List" recommended by CHPA in this document.

FDA Question 4. Because so much of our nation's food supply is either imported or exported, what do you believe should be the highest priority international activities?

CHPA Response.

- No comment.

Conclusion

In conclusion, CFSAN should place safety first – enforcement, GMPs and AERs when setting its priorities for program activities in the year 2000. The refinement of the infrastructure of the Office of Special Nutritionals and other components of CFSAN should be part of this safety priority.

Sincerely yours,

R. William Soller

for R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

Leila Saldanha, Ph.D., R.D.
Vice President – Nutritional Sciences

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